NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HENRIETTA S. O'BRYANT and BOBBY J. O'BRYANT,

Plaintiffs,

v.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

Civil Action No. 20-2361 (MAS) (DEA)

MEMORANDUM OPINION

SHIPP, District Judge

This matter comes before the Court on several motions by Plaintiffs Bobby J. O'Bryant and Henrietta S. O'Bryant (collectively, "Plaintiffs") and Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson ("J&J" and collectively with Ethicon, "Defendants").

Beginning with Plaintiffs, Plaintiffs *first* filed a Motion to Exclude Opinions and Testimony of John Wagner, M.D. ("Dr. Wagner"). (ECF No. 57.) Defendants opposed (ECF No. 72) and Plaintiffs replied (ECF No. 77). *Second*, Plaintiffs filed a Motion to Exclude Opinions and Testimony of Christopher J. Winfree, M.D. ("Dr. Winfree"). (ECF No. 58.) Defendants opposed (ECF No. 73) and Plaintiffs replied (ECF No. 76). *Third*, Plaintiffs filed a Motion to Exclude Opinions and Testimony of Thomas C. Wright, Jr., M.D. ("Dr. Wright"). (ECF No. 59.) Defendants opposed (ECF No. 74) and Plaintiffs replied (ECF No. 78).

As to Defendants' volley of motions, Defendants *first* filed a Motion to Limit Case-Specific Opinions and Testimony of Alan Garely, M.D. ("Dr. Garely"). (ECF No. 60.) Plaintiffs opposed (ECF No. 69) and Defendants replied (ECF No. 79). *Second*, Defendants filed a Motion

to Limit General Causation Opinions and Testimony of Alan Garely, M.D. (ECF No. 61.) Plaintiffs opposed (ECF No. 70) and Defendants replied (ECF No. 80). *Finally*, Defendants filed a Motion to Limit Testimony of Barnd Klosterhalfen ("Dr. Klosterhalfen"). (ECF No. 62.) Plaintiffs opposed (ECF No. 71) and Defendants replied (ECF No. 80). The Court has carefully considered the parties' submissions and decides the matter without oral argument under Local Civil Rule 78.1.

I. BACKGROUND

This is a case about allegedly defective medical devices. Plaintiffs are citizens of Tennessee. (Second Am. Compl. ¶¶ 1-2, ECF No. 65.) In 2008, Plaintiff Henrietta S. O'Bryant underwent implantation of a mesh device known as the Prolift Total Pelvic Floor Repair System ("Prolift") during surgery performed by Dr. Alfredo Nieves ("Dr. Nieves") in Chattanooga, Tennessee to treat her pelvic organ prolapse ("POP"). (*Id.* ¶ 3; Pls.' Mot. to Exclude Dr. Wagner 1, ECF No. 57.)[1] The Prolift was sold, marketed, and/or designed by Defendants. (Second Am. Compl. ¶ 3.) The Prolift allegedly contracted and deformed in Plaintiff's body, created excessive tension on the anterior and posterior aspects of the mesh, and eroded into the wall of Plaintiff's rectum and into her rectum. (*Id.* ¶ 5.) Plaintiff subsequently had surgery, performed by Dr. John Miklos ("Dr. Miklos") in Atlanta, Georgia, to explant the mesh device (*Id.* ¶¶ 4-5.) Dr. Miklos was unable to remove the Prolift device in its entirety, and portions of the product remain embedded in Plaintiff's body. (*Id.* ¶ 5.) Despite the removal surgery and other medical treatments, "Plaintiff continues to suffer from severe pelvic pain and other complications." (*Id.* ¶ 6.)

On October 21, 2013, Plaintiffs filed suit in a multi-district litigation ("MDL") case (*In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327) related to two allegedly

[1] All references to "Plaintiff" in the singular refer to Henrietta S. O'Bryant unless further specified.

defective medical devices, including the Prolift. (Pls.' Mot. to Exclude Dr. Wagner 2; *see generally* Compl., ECF No. 1.) After this case was selected for a trial work-up "wave" in the MDL, the parties stipulated to a voluntary dismissal without prejudice of the MDL case in February 2019. (Pls.' Mot. to Exclude Dr. Wagner 2.) Unable to reach a mutually agreeable resolution, Plaintiffs refiled in this Court on March 6, 2020. (*Id.*; *see generally* Compl.) After a series of motion practice before the Court (ECF Nos. 11-64), Plaintiffs arrived at a Second Amended Complaint asserting the following claims against Defendants: negligence (Count I); strict liability – failure to warn (Count II); strict liability – design defect (Count III); loss of consortium (Count IV); and punitive damages (Count V). (Second Am. Compl. ¶¶ 54-90.)

Plaintiffs and Defendants now move to preclude certain opinions and testimony offered by each other's experts.

II. LEGAL STANDARD

A. Choice of Law

Defendants' motions require the Court to first determine the applicable substantive law. "[I]n a diversity action, a district court must apply the choice of law rules of the forum state to determine what law will govern the substantive issues of a case." *Warriner v. Stanton*, 475 F.3d 497, 499-500 (3d Cir. 2007). Because New Jersey is the forum state, New Jersey's choice-of-law rules apply. (*See id.* at 500.)

New Jersey's choice of law rules follow the Restatement (Second) of Conflict of Laws. *See P. V. v. Camp Jaycee*, 962 A.2d 453, 460-61 (N.J. 2008). "[T]he first step is to determine whether an actual conflict exists." *Id.* at 460. An "actual conflict" exists when choosing between two states' laws would be "outcome determinative." *McCarrell v. Hoffmann-La Roche Inc.*, 227 N.J. 569, 584 (2017) (citing *Schmelzle v. ALZA Corp.*, 561 F. Supp. 2d 1046, 1048 (D. Minn. 2008)); *see Camp Jaycee*, 962 A.2d at 460-61 (finding conflict where New Jersey law made charitable organizations

immune from most forms of tort liability whereas Pennsylvania law subjected charitable organizations to tort liability). The Court must determine whether a conflict exists "on an issue-by-issue basis." *Rowe v. Hoffmann-La Roche, Inc.*, 189 N.J. 615, 621 (2007) (quotations and citations omitted). "If there is no actual conflict, then the choice-of-law question is inconsequential," and the Court would apply the law of the forum state—here, New Jersey—"to resolve the disputed issue." *Id.*

If a conflict exists, "the Court must determine which state has the most significant relationship to the claim, by weigh[ing] the factors set forth in the Restatement section corresponding to the plaintiff's cause of action." *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 699 (D.N.J. 2011) (alteration in original) (quotations and citation omitted). "In an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship[.]" *Restatement (Second) of Conflict of Laws* § 146; *see Camp Jaycee*, 962 A.2d at 460 ("[T]he law of the state of the injury is applicable unless another state has a more significant relationship to the parties and issues.").

B. *Daubert* Motions

Federal Rule of Evidence 702 governs the admission of expert testimony. *See* Fed. R. Evid. 702. Federal Rule of Evidence 702 provides that a witness who is qualified as an expert may testify in the form of an opinion or otherwise if:

> (a) the expert's . . . specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702(a)-(d). Federal Rule of Evidence 703 provides in part that "[a]n expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703.

As established under *Daubert*, the trial court serves as a "gatekeeper" tasked with "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand" in deciding whether that testimony is admissible. *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 597 (1993); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-48 (1999) (applying *Daubert* standard to all expert testimony). To accomplish that duty, courts must evaluate three factors in deciding whether to admit the testimony, including whether: (1) the expert is qualified; (2) the expert's testimony is reliable; and (3) the expert's testimony is helpful to the trier of fact, i.e., "fit." *See United States v. Schiff*, 602 F.3d 152, 172 (3d Cir. 2010); Fed. R. Evid. 702.

Particularly relevant here, in determining whether proposed expert testimony is reliable, the trial court should examine:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994); *see also Schneider ex rel Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003). Each step of the expert's analysis must be reliable, including "the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) (internal quotation marks omitted) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)).

The party offering the expert testimony must prove these three requirements by a preponderance of the evidence. *Mahmood v. Narciso*, 549 F. App'x 99, 102 (3d Cir. 2013) (citing *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999)). But proponents of expert testimony need not "prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000) (internal quotation marks omitted) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 744). Reliability is the touchstone.

The district court, exercising its discretion, serves as a gatekeeper to prevent expert testimony that falls short of these requirements from reaching the jury. *See Daubert*, 509 U.S. at 592-95. Nevertheless, the "basic standard of relevance . . . is a liberal one." *Id.* at 587. Within the principles outlined above, the Court has "the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Kumho Tire*, 526 U.S. at 142 (emphasis in original) (internal citation omitted).

III. DISCUSSION

A. Choice of Law

With the standards set, the Court turns first to whether a conflict exists between the applicable product liability laws in New Jersey, where Defendants are incorporated and maintain their headquarters, and Tennessee, Plaintiffs' home state and where Dr. Nieves implanted Plaintiff's Prolift device. (Second Am. Compl. ¶¶ 1-3, 8.) In New Jersey, plaintiffs must bring "claims for 'harm caused by a product'" under the New Jersey Products Liability Act ("NJPLA"), §§ N.J.S.A. 2A:58C-1, *et seq. Sinclair v. Merck*, 195 N.J. 51, 65-66 (2008) (concluding products liability claim must be brought under the NJPLA because "the Legislature expressly provided . . . that claims for 'harm caused by a product' are governed by the [NJ]PLA 'irrespective of the theory

underlying the claim'") (quoting § N.J.S.A. 2A:58C-1(b)(3)); *Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 374 (D.N.J. 2019) ("The NJPLA is the 'sole basis of relief under New Jersey law available to consumers injured by a defective product.'") (quoting *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991)). "[N]egligence and breach of [implied] warranty are [not] viable" as separate claims for injuries caused by defective products. *Oquendo v. Bettcher Indus., Inc.*, 939 F. Supp. 357, 361 (D.N.J. 1996) (citing *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398 (App. Div. 1991), *aff'd*, 118 F.3d 1577 (3d Cir. 1997)). Tennessee similarly has a product liability act, the Tennessee Product Liability Act ("TPLA"), which subsumes common law claims. Tenn. Code Ann. § 29-28-102(6); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013) ("[A]ll of [plaintiffs'] claims fall within the purview of the TPLA as a 'product liability action.'. . . This is true despite their most artful efforts to dress up a relatively simple failure-to-warn claim in a great variety of tort and contract causes of action.").

Yet while New Jersey and Tennessee both have a product liability act that provides for strict liability, an actual conflict exists. Numerous courts have recognized that while New Jersey and Tennessee both recognize strict liability, their product liability laws are different in certain respects. For example, in a case that directly compared New Jersey and Tennessee product liability statutes, the district court recognized that Tennessee's statute of repose would bar the plaintiff's products liability claims whereas New Jersey had no statute of repose applicable to the plaintiff's claims, thus creating a conflict of law. *Wahl v. Gen. Elec. Co.*, 983 F. Supp. 2d 937, 945 (M.D. Tenn. 2013), *aff'd*, 786 F.3d 491 (6th Cir. 2015); *see In re Accutane Litig.*, 235 N.J. 229, 257 (N.J. 2018) (finding a conflict between New Jersey and the other jurisdictions at issue, including Tennessee, by "proceed[ing] under the assumption that the application of [the NJPLA] may lead to an outcome different from the application of the laws of those other jurisdictions"); *see also Butera v. Honeywell Int'l, Inc.*, No. 18-13417, 2020 WL 64568, at *2 (D.N.J. Jan. 6, 2020)

(applying the law of each plaintiff's home state to the claims of the plaintiffs in a product liability action even when defendant's principal place of business was in New Jersey). Even a cursory look at the intricacies of the substantive claims at issue in this case buttresses this Court's finding of a conflict. For example, New Jersey law requires proof of a reasonable alternative design as part of a plaintiff's prima facie case for a design defect. *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 823-24 (D.N.J. 2019) ("Though there is no 'per se rule that [p]laintiffs must, under all circumstances, provide a reasonable alternative design,' a plaintiff must plead either that the product's risk [of harm] outweighs its [utility], or that an alternate design exists, in order to state a claim for a design defect under the [NJPLA].") (citing, among others, *Mendez v. Shah*, 28 F. Supp. 3d 282, 297-98 (D.N.J. 2014)) (alterations in original). By contrast, the existence of a safer alternative design appears to be relevant (but not dispositive) for a design-defect claim under Tennessee law. *Brown v. Raymond Corp.*, 318 F. Supp. 2d 591, 599 (W.D. Tenn. 2004), *aff'd*, 432 F.3d 640 (6th Cir. 2005).

The key question, then, is where Plaintiffs' injuries occurred. In product liability cases, New Jersey courts have found that "interests of comity, the interests of the parties, the purposes of this field of law, and the respective governmental interests favored the state where the party was allegedly injured . . . . " *Yocham v. Novartis Pharms. Corp.*, 736 F. Supp. 2d 875, 882-83 (D.N.J. 2010) (citing cases); *see, e.g.*, *Deemer v. Silk City Textile Mach. Co.*, 475 A.2d 648, 652-53 (N.J. Super. Ct. App. Div. 1984) (finding North Carolina law applied to product liability claim where plaintiff suffered injury in North Carolina, but where the product was manufactured in New Jersey by a manufacturer organized in New Jersey); *Dandy v. Ethicon Women's Health & Urology*, No. 20-431, 2022 WL 1284735, at *5 (D.N.J. Apr. 29, 2022) (finding "a strong presumption" that the state law where plaintiff suffered the injury governs, even though "certain conduct that allegedly caused [p]laintiff's injuries occurred in New Jersey").

Because the surgical implant of the pelvic mesh product occurred in Tennessee, and no other state has a more significant relationship to this claim, at this stage the Court makes a preliminary determination that Tennessee substantive law applies if it is in conflict with New Jersey law, as it does for the design-defect claim implicated in some of the Motions below.

B. Plaintiffs' *Daubert* Motions

As mentioned, Plaintiffs move to exclude the opinions and testimony of Defendants' experts, Drs. Wagner, Winfree, and Wright. The Court considers each Motion in turn.

1. The Opinions and Testimony of Dr. Wagner

Plaintiffs move to exclude, as irrelevant, Dr. Wagner's opinions regarding whether the mesh removal surgery performed by Dr. Miklos caused or contributed to any injury experienced by Plaintiff. (*See generally* Pls.' Mot. to Exclude Dr. Wagner.) Plaintiffs take issue with the fact that although Dr. Wagner acknowledged that mesh removal surgery was necessary due to Plaintiff's rectal erosion, and that removal surgery involves significant tissue dissection, Dr. Wagner claims in his case-specific expert report that the "unnecessary" extent of the surgery that took place likely contributed to Plaintiff's ongoing pelvic pain. (*See id.* at 3 (citing Dr. Wagner Case-Specific Expert Rep. 61-62 ¶¶ 13-14, ECF No. 57-2).) Plaintiffs rely on *Hurt v. Coyne Cylinder Co.*, among others, for the proposition that under Tennessee law, intervening cause and abnormal use are affirmative defenses as to which Defendants bear the burden of proof, and both require proof of non-foreseeability. (*Id.* at 4 (citing *Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1325 (6th Cir. 1992).) Because Defendants do not contend that Dr. Miklos was negligent, and it is "undisputed that the mesh removal surgery by Dr. Miklos was done within the standard of care,"

Plaintiffs argue that Dr. Miklos's non-negligent surgery was reasonably foreseeable and, thus, Dr. Wagner's testimony would be "irrelevant" and speculative. (*Id.* at 5-6.)[2]

Defendants, on the other hand, contend that "a jury need not find that Dr. Miklos was negligent for it to determine that his actions were a cause in fact of [Plaintiff]'s injuries." (Defs.' Opp'n to Mot. to Exclude Dr. Wagner 3, ECF No. 72.) Defendants further argue that a reasonable jury could find Dr. Miklos's allegedly overly extensive surgery was not reasonably foreseeable. (*Id.* at 3-4.) And Defendants dispute Plaintiffs' notion that Dr. Wagner's opinions are speculative here, but rather argue that they are well supported by Plaintiff's medical records and the medical literature. (*Id.* at 4-5.)

The Court finds that Dr. Wagner's potential testimony and opinions are not unduly speculative. Indeed, apart from relying on his own clinical experience, Dr. Wagner cites several medical journals to inform his opinion that complete removal of the mesh is unnecessary. (Dr. Wagner Expert Rep. 61-62; *see In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2018 WL 3545136, at *3 (S.D. W. Va. July 23, 2018) ("This extensive clinical experience, combined with his review of peer-reviewed literature, qualifies Dr. Wagner to opine on mesh's reaction to and effect on the human body.").) In addition, whether Dr. Miklos's revision surgery—with all the risks that surgery generally entails—contributed to Plaintiff's claimed injuries is relevant to determining the scope of liability, regardless of whether New Jersey or Tennessee substantive law applies at this juncture. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265

[2] Plaintiffs do not explicitly challenge Dr. Wagner's qualifications. The Court nonetheless finds Dr. Wagner qualified to testify as to the cause of Plaintiff's injuries. Dr. Wagner has practiced urogynecology for approximately 30 years and is board certified in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology. (Dr. Wagner CV 1, ECF No. 72-2.) Dr. Wagner has taught pelvic surgery to resident physicians and has served as a Clinical Associate Professor. (*Id.* at 2-4.) Perhaps most crucially, Dr. Wagner has implemented approximately 800-1,000 Prolift and Prolift +M devices, as well as explanted pelvic mesh devices. (*Id.*; Dr. Wagner Expert Rep. 6, 32, ECF No. 72-3.)

(4th Cir. 1999) (explaining that generally, "[t]he alternative causes suggested by a defendant 'affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony'") (internal citation omitted); *Olszeski v. Ethicon Women's Health & Urology*, No. 5:19-1787, 2022 WL 1063737, at *3 (N.D. Ohio Apr. 8, 2022) (opinion on whether removal of medical device TVT-O was "'medically unnecessary'" is a matter for cross-examination, not exclusion). Thus, the Court denies Plaintiffs' Motion to Exclude the Opinions and Testimony of Dr. Wagner. Should Plaintiffs have a more tailored objection at trial, or believe Dr. Wagner has strayed too far in his testimony, they are free to raise an objection then.

2. The Opinions and Testimony of Dr. Winfree

Plaintiffs move to exclude Dr. Winfree from offering any testimony regarding his "Opinion No. 9," ("Opinion No. 9") which generally states that "there is no scientific evidence to support the other mesh-related mechanisms that Dr. Garely claims have caused [Plaintiff]'s pelvic pain." (Pls.' Mot. to Exclude Dr. Winfree 3, ECF No. 58 (quoting Dr. Winfree Expert Rep. 29, ECF No. 58-2).) Plaintiffs challenge these opinions on the bases that Dr. Winfree lacks the requisite qualifications and that they are impermissible legal conclusions. The Court addresses these bases for exclusion in turn.

a. Qualifications

Plaintiffs' first two objections pertain to Dr. Winfree's qualifications. *First*, Plaintiffs claim Dr. Winfree has "no expertise to offer any opinion regarding whether there are Prolift-related mechanisms that have caused or contributed to Plaintiff's chronic pelvic pain." (*Id.* at 3.) *Second*, Plaintiffs claim that Dr. Winfree's own opinion that Dr. Garely's opinion is "speculative" or not supported by sufficient evidence should be excluded because Dr. Winfree has no expertise to make this assertion. (*Id.* at 6.)

Plaintiffs begin by asserting that Dr. Winfree is not a pelvic pain primary care physician, gynecologist, or urologist. (*Id.* (citing Dr. Winfree 2/11/22 Dep. Tr. 24, ECF No. 58-1).) He has neither authored literature related to vaginal mesh nor treated certain complications allegedly experienced by Plaintiff, such as POP. (*Id.* at 3 (citing Dr. Winfree 2/11/22 Dep. Tr. 23, 27-28, 30-33, 76).) And, among other issues, Plaintiffs highlight that Dr. Winfree lacks certain relevant training, such as on how to implant a Prolift device. (*Id.* (citing Dr. Winfree 2/11/22 Dep. Tr. 27-28).) Given this lack of expertise, Plaintiffs contend that he should not be permitted to critique Plaintiffs' expert, Dr. Garely, who is a pelvic surgeon, regarding the causal connection between Prolift and Plaintiff's pelvic pain. (*Id.* at 5-6.)

The Court disagrees with Plaintiffs. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). As Defendants note, Dr. Winfree "was not retained to discuss the intricacies of prolapse surgery," but rather, to offer opinions on the causes of Plaintiff's pain. (Defs.' Opp'n to Mot. to Exclude Dr. Winfree 2-3, ECF No. 73.) And Dr. Winfree is well qualified to opine on pain causation.[3] Indeed, Plaintiffs do not challenge Dr. Winfree's qualifications as they pertain to the field of chronic pain. Relying on this experience, as well as his review of Plaintiff's medical records and the medical literature, Dr. Winfree opines on the lack of evidence to support a finding that Plaintiff's peripheral nerves are sufficiently

[3] Dr. Winfree is board certified in neurological surgery by the American Board of Neurological Surgery. (Dr. Winfree Expert Rep. 2.) For eight years, Dr. Winfree was Director of the Center for Chronic Pelvic Pain at Columbia University College of Physicians and Surgeons and is currently an Assistant Professor of Neurological Surgery, Neurosurgery Residency Associate Program Director, Director of the Center for Neurosurgical Pain Management, and Director of the Center for Peripheral Nerve Surgery at Columbia. (*Id.*) He specializes in peripheral nerve surgery and the neurological treatment of chronic pain disorders, and has extensive experience with treating chronic pain patients, including those with pelvic pain. (*Id.*) In addition, Dr. Winfree has authored or coauthored approximately fifty articles in peer-reviewed medical journals on topics in neurosurgery, including the treatment of chronic pelvic pain. (*Id.*)

compressed, which he contends would result in pain. (Dr. Winfree Expert Rep. 30.) Ultimately, Dr. Winfree concludes that the complications of Plaintiff—a chronic pain patient—"cannot be attributed to a single procedure or event, but rather is the result of years of chronic pain that predated her mesh implant surgery." (*Id.*) Given Dr. Winfree's extensive experience studying chronic pelvic pain, the Court concludes that he satisfies the qualification prong as an expert on the matters at hand, at least as to his testimony in "Opinion No. 9." *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 714 (S.D. W. Va. 2014) (finding a doctor who, among other qualifications, headed the Division of Laparoscopy and Pelvic Pain at a university qualified to opine on the etiology of problems associated with the implantation of mesh products in gynecologic surgery). Thus, the Court denies Plaintiffs' Motion on this point.

b. Legal Conclusions

Plaintiffs additionally challenge Dr. Winfree's opinions that Dr. Garely's opinions are "speculative," which Plaintiffs assert are improper opinions not only because of Dr. Winfree's lack of expertise—a contention that this Court has just rejected—but also on the grounds that such opinions form a legal conclusion. The Court disagrees. "[A]n expert witness generally may not provide legal opinions . . . ." *Lozano v. City of Hazleton*, 241 F.R.D. 252, 256 (M.D. Pa. 2007). The "use of legal terms of art or legal conclusions" by an expert "could lead the jury to be prejudicial" against the opposing party. *Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). But here, it appears that Plaintiffs' issue is a mere matter of word choice. The Court finds Dr. Garely's use of the term "speculative" amounts to a remark on the alleged lack of evidence behind Dr. Winfree's opinions, rather than a "legal conclusion." Indeed, if the Court were to prohibit Dr. Garely from use of the word "speculative," he would simply substitute different terminology that would have the same effect on the jury. The Court, accordingly, denies Plaintiffs' Motion on this point.

3. The Opinions and Testimony of Dr. Wright

Next, Plaintiffs move to exclude the opinions and testimony of Dr. Wright pertaining to several areas. (*See generally* Pls.' Mot. to Exclude Dr. Wright, ECF No. 59.) The Court addresses each one in turn.

a. Opinions on the treatment of POP

First, Plaintiffs contend that Dr. Wright should be precluded from offering any opinions related to the available treatments for POP or the alleged rates of success or failure for various treatments of POP because, among other reasons, Dr. Wright has no experience regarding pelvic surgery or pelvic mesh. (*Id.* at 5.) Because Defendants concede that Dr. Wright will not opine on these two factual topics, the Motion is denied as moot on this point. (*See* Defs.' Opp'n to Mot. to Exclude Dr. Wright 1-2, ECF No. 74 ("However, the point is moot, because Ethicon does not plan on introducing opinion testimony from Dr. Wright [on these factual areas].").)

b. Opinions on mesh product design characteristics

Second, Plaintiffs argue that Dr. Wright, an anatomic pathologist, lacks the expertise to testify about any characteristics of mesh product design, including pore size or "effective pore size" and the relationship of any mesh design characteristic with potential complications for patients, including Plaintiff. (Pls.' Mot. to Exclude Dr. Wright 6-8.)[4] Dr. Wright seeks to offer certain opinions on how factors, such as porosity and pore size, influence the body's response to implanted synthetic mesh. (Dr. Wright Expert Rep. 4-5, ECF No. 59-2.)

[4] Plaintiffs make a duplicative argument that Dr. Wright is unqualified to offer opinions on the cause of complications experienced by Plaintiff. (*See id.* at 10-11.) The Court considers both points together.

The Court disagrees with Plaintiffs. Plaintiffs do not challenge Dr. Wright's qualifications as an anatomic pathologist, for good cause.[5] District courts have repeatedly found pathologists qualified to testify about the pathology of mesh explants despite a lack of training in polymer science or in testing mesh products. *See, e.g.*, *Frankum v. Bos. Sci. Corp.*, No. 2:12-904, 2015 WL 1976952, at *24 (S.D. W. Va. May 1, 2015); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-5762, 2014 WL 4851989, at *20 (S.D. W. Va. Sept. 29, 2014). Here, Dr. Wright reviewed the pathology slides, medical records, and underlying reports to conclude, based on his pathology analysis, that "there is nothing in the histology that can be correlated to the Plaintiff's alleged symptoms." (Dr. Wright Expert Rep. 8, ECF No. 74-4; *see Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D. W. Va. 2014) (describing "reliable pathology methods—he reviewed slides, considered the possible causes [], and came to a diagnostic conclusion").) And Defendants concede that Dr. Wright "does not intend to provide mesh 'design' opinions generally, except to the extent they are relevant to his pathology opinions" or in rebuttal. (Defs.' Opp'n to Mot. to Exclude Dr. Wright 4.) Because the Court agrees that Dr. Wright's experience and pathology methods qualify him to reliably offer his testimony on mesh product design and its effects, the Court denies Plaintiffs' Motion on these grounds.

c. Opinions on patients other than Plaintiff

Third, and finally, Plaintiffs contend Dr. Wright should be precluded from offering any opinion regarding other mesh patients because of Dr. Wright's lack of expertise in the field of

[5] Dr. Wright is an anatomic pathologist with experience as a researcher at Harvard Medical School and as an attending pathologist at Brigham and Women's Hospital, and is fellowship trained in "gynecologic/obstetric pathology." (Dr. Wright 3/29/16 Dep. Tr. 6:3-7, 9:3-7, 10:1-18, ECF No. 74-2.) Dr. Wright was once the Director of the Division of Gynecological, Obstetrical, and Cytological Pathology at Columbia University, where he was also an attending pathologist and treated patients in a clinical setting. (*Id.* at 7:22-8:2, 16:15-19.) In total, Dr. Wright has over 35 years of experience as an anatomic pathologist and is board certified. (*See generally* Dr. Wright CV, ECF No. 74-3.)

surgical mesh and a lack of factual basis in the record for Dr. Wright's opinions. (Pls.' Mot. to Exclude Dr. Wright 8-9.) But this argument takes Dr. Wright's statements out of context. Dr. Wright's statements are not an attempt to present testimony regarding the "hypothetical experiences of 'millions of women' who are not before this Court," but rather, to rebut the testimony of Dr. Klosterhalfen. (*Id.* at 10 (*see* Dr. Wright First Supp. Rep. 5, ECF No. 59-4).) And as explained above, Dr. Wright is qualified to offer his opinions on the pathological responses to mesh implants. Furthermore, Dr. Wright relies on medical literature to inform his rebuttal statements. (*See* Dr. Wright First Supp. Rep. 4 (citing three different medical journals).) Thus, the Court denies Plaintiffs' Motion on this point.

C. Defendants' *Daubert* Motions

The Court now turns to Defendants' motions. Defendants contend that this Court should limit the case-specific and general causation opinions and testimony of Plaintiffs' experts, Drs. Garely and Klosterhalfen. The Court considers each *Daubert* Motion in turn.

1. The Case-Specific Opinions and Testimony of Dr. Garely

Defendants first move to limit numerous case-specific opinions and testimony of Dr. Garely. (*See* Defs.' Mot. to Limit Case-Specific Dr. Garely 1, ECF No. 60-18.) The Court addresses each opinion and the grounds for its exclusion in turn.

a. Opinions on pudendal neuralgia and tailbone pain

To begin, Defendants contend that Dr. Garely does not have a reliable basis for his opinion that Plaintiff has pudendal neuralgia/tailbone pain from the Prolift implant. (*Id.* at 4.) *First*, they contend his methodology is unreliable because Dr. Garely is not familiar with the Nantes criteria ("Nantes criteria") that must be present in order to diagnose neuralgia by nerve entrapment. (*Id.* at 4-5 (citing Dr. Garely 7/16/21 Dep. Tr. 152:21-153:17, ECF No. 60-4 ("I'm not familiar with it.").) This apparent lack of familiarity is curious, Defendants allude, given that Dr. Garely cited a paper

by Dr. Michael Hibner, M.D., *et al.* (the "Dr. Hibner Paper") in his supplemental report that explicitly discusses the Nantes criteria; Defendants argue that this inconsistency (and Dr. Garely's overall lack of familiarity) renders his opinions unreliable. (*See id.* at 5 (citing Dr. Hibner Paper, ECF No. 60-5).)

The Court is not convinced by Defendants' argument. "Dr. Garely is board-certified in female pelvic medicine and reconstructive surgery, has written peer-reviewed publications specific to pelvic floor mesh, has treated patients with mesh complications, and has provided consultation services to manufacturers for the development of pelvic mesh implants." *Arevalo v. Coloplast Corp.*, No. 19-3577, 2020 WL 3958505, at *5 (N.D. Fla. July 7, 2020), *reconsideration denied*, No. 3:19-3577, 2020 WL 6018933 (N.D. Fla. Oct. 6, 2020) (finding Dr. Garely qualified to offer testimony about medical design issues in related litigation). It is not a stretch to find that Dr. Garely's extensive clinical experience treating patients with mesh complications enables him to apply that experience to the diagnosis of Plaintiff. During his deposition, Dr. Garely testified that he has seen patients in his clinical practice come in with Prolift-related complications, with "pain distribution along the way that the pudendal nerve travels." (Dr. Garely 7/16/21 Dep. Tr. 152:4-14.) Dr. Garely further testified that eighty percent of his time is devoted to the treatment of prolapse and incontinence. (*Id.* at 33:4-7.) And while the Dr. Hibner Paper does describe the Nantes criteria as "widely accepted," the paper also mentions that these criteria should be considered "in conjunction with clinical experience and physical findings." (Dr. Hibner Paper 148.) Dr. Garely makes explicitly clear that in forming his opinions, he has relied upon "the medical principles and methods that [he] [uses] in [his] medical practice as a specialist in urogynecology and pelvic reconstructive surgery" as applied to the medical records (including that of Plaintiff's treating physicians) he has reviewed in this case. (Dr. Garely Expert Rep. 1, ECF No. 60-2; *see Kumho Tire*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion

from a set of observations based on extensive and specialized experience.").) Plaintiffs are free to cross examine Dr. Garely to explore the bases of his conclusions and demonstrate any perceived flaws to the jury. *Robinson v. Ethicon, Inc*, No. 20-03760, 2022 WL 666400, at *6 (S.D. Tex. Mar. 4, 2022) (rejecting argument that lack of familiarity with the Nantes criteria renders unreliable the doctor's opinion on whether plaintiff suffered from pudendal neuralgia). Thus, the Court does not find Dr. Garely's methodology unreliable and denies Defendants' Motion on this point.

Second, Defendants argue that Dr. Garely "has no objective testing" like magnetic resonance ("MR") neurography "to support his pudendal neuralgia opinion," which underscores the need for Plaintiff to meet the subjective Nantes criteria in order for Dr. Garely's opinion to be reliable. (Defs.' Mot. To Limit Case-Specific Dr. Garely 8 (citation omitted).) For the same reasons discussed in the previous paragraph, the Court denies Defendants' Motion on this point.

Third, Defendants contend that the mechanism of pudendal injury described by Dr. Garely is not reliably supported by data. (*Id.*) Defendants essentially argue that Dr. Garely's inability to point to a single study to support his theory renders it unreliable. (*Id.* at 8-9.) But again, Dr. Garely's personal experience and reliance on internal documents "may, theoretically, provide a reasonable basis for expert testimony." *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582214, at *4 (S.D. W. Va. Sept. 1, 2016) (denying Ethicon's arguments regarding Dr. Garely on similar grounds); *see Kumho Tire*, 526 U.S. at 156. Thus, the Court denies Defendants' Motion on this point.

Fourth, Defendants argue that Dr. Garely's reliance on the causation opinions of Plaintiff's pain specialists is unreliable. (Defs.' Mot. to Limit Case-Specific Dr. Garely 9.) Dr. Garely relies, in part, on the depositions of Plaintiff's treating physicians, including Drs. Alex Childs ("Dr. Childs"), Gregory Ball ("Dr. Ball"), and John Blake ("Dr. Blake"). (Dr. Garely Supp. Rep. 1, ECF No. 60-3.) Yet Dr. Garely explicitly states that the diagnoses of these pain specialists "provide[d]

additional bases and support for my opinions regarding the case of [Plaintiff]'s permanent pelvic pain." (*Id.* at 5.) For the reasons stated above, the Court denies Defendants' Motion on this point.

b. Opinion on Plaintiff's rectovaginal fistula in 2017

Defendants next challenge as unreliable Dr. Garely's opinion that the Prolift caused Plaintiff to experience a rectovaginal fistula in 2017. (Defs.' Mot. to Limit Case-Specific Dr. Garely 13.) Defendants contend that Dr. Garely lacks an objective basis for this opinion as the only bases he relies upon in forming these opinions are a CT scan and the report of a physician who read that CT scan. (*Id.* at 13 (citing Dr. Garely 7/16/21 Dep. Tr. 122-123).) Meanwhile, two other physicians who examined Plaintiff found she did not have a fistula. (*Id.*)

The Court disagrees. Dr. Garely "personally reviewed the CAT scan" alongside "the radiologist who sits with the American Academy of Radiology pelvic floor committee, where this is what they do[,]" and both concluded that the findings of the scan indicated a fistula. (Dr. Garely 7/16/21 Dep. Tr. 131:10-25.) Dr. Garely has previously written in an article about vesicovaginal fistulas that "imaging studies are necessary" for "complete evaluation of the number and location of fistulas." (*Id.* at 128:6-17, 129:3-14.) Defendants do not sufficiently demonstrate that Dr. Garely's review of the CAT scan was faulty or inappropriate as a basis for diagnosing fistulas. *See Walker v. Gordon*, 46 F. App'x 691, 695 (3d Cir. 2002) ("[T]he role of the District Court is simply to evaluate whether the *methodology* utilized by the expert is reliable, i.e., whether, when correctly employed, that methodology leads to testimony helpful to the trier in fact.") (emphasis in original). Instead, Defendants' argument concerns a classic battle of the experts over their interpretation of certain evidence—precisely the sort of job more appropriate for the jury. *See Cadmus v. Aetna Cas. & Surety Co.*, 1996 WL 652769, at *2 (6th Cir. Nov. 7, 1996) (unpublished) (citation omitted). "The fact that an expert's opinion is contradicted or disputed by other evidence in the record does not necessarily warrant exclusion of the expert's opinion. Contrary evidence goes to

the weight, and not the admissibility, of the expert testimony." *Mims v. Wright Med. Tech., Inc.*, No. 11-213, 2012 WL 12835870, at *2 (N.D. Ga. May 11, 2012) (citation omitted). Thus, the Court denies Defendants' Motion on this point.

c. Opinions on Plaintiff's pelvic pain before 2012

Next, Defendants dispute as unreliable Dr. Garely's opinions suggesting Plaintiff experienced pelvic pain before 2012. (Defs.' Mot. to Limit Case-Specific Dr. Garely 14.) Defendants contend that any such opinion is belied by the testimony of Plaintiff's contemporaneous treating physicians from 2008 to 2012, who claimed that Plaintiff never reported pelvic pain during their treatment of her. (*Id.* at 14-15.) Defendants also note that Dr. Garely relied, in part, on the testimony of Plaintiff's physicians Drs. Ball, Childs, and Blake, who did not treat Plaintiff during this time frame—instead, these doctors made their assessment connecting Plaintiff's pelvic pain to the Prolift based on the subjective history Plaintiff provided to them that her pain started after her implant surgery. (*Id.* at 15 (citations omitted).)

The Court disagrees. Dr. Garely is permitted to rely on the medical records in this case, including the testimony of Plaintiffs' more recent physicians. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742 (explaining that an "expert's opinions must be based on the methods and procedures of science") (internal quotation marks omitted). In any event, individuals typically provide their subjective history of pain to their physicians, who may then base their diagnoses off this history in turn. Any objections by Defendants on the factual bases for these records go to the weight, rather than the admissibility of Dr. Garely's testimony. The Court denies Defendants' Motion.

d. Opinions on Plaintiff's permanency of injury

Defendants move to exclude Dr. Garely's opinions on the permanency of Plaintiff's injury because they are unreliable and unhelpful to the jury. (Defs.' Mot. to Limit Case-Specific Dr. Garely 15.) Defendants again contend that Dr. Garely's reliance on statements from Drs. Childs,

Ball, and Blake to inform his opinions renders them speculative, as two of the doctors have not seen Plaintiff since 2018 or earlier, and the other has primarily performed injections on Plaintiff unrelated to the mesh and Plaintiff's pelvic pain. (*Id.* at 16.) For the same reasons discussed above, the Court denies Defendants' Motion on this point.

e. Opinions on alleged safer alternative designs

Finally, Defendants contend that the Court should exclude the opinions of Dr. Garely regarding safer alternative designs for the mesh implant in lieu of Prolift because his opinions are unreliable and irrelevant. (*Id.* at 16-17.) Defendants first contend that alternative surgical procedures without mesh are not relevant here. (*Id.* at 17.)

The Court agrees that evidence of alternative surgeries should be excluded due to a lack of relevance. In *Hosbrook*, the district court, applying Tennessee law, found that evidence of alternative surgical procedures "is irrelevant and would create confusion for the jury" because these procedures have no bearing on whether the Prolift device was unreasonably dangerous; it found unconvincing Ethicon's argument that Prolift was both a product and a procedure. *Hosbrook v. Ethicon, Inc.*, No. 20-88, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021). The Court concurs. At the end of the day, under the applicable Tennessee law, Plaintiffs must thus establish the implant was "in a defective condition" or "unreasonably dangerous" at the time it left the control of the manufacturer or seller—alternative procedures have no bearing on this standard. *See id.* (internal citation and quotation omitted); *see also Dandy*, 2022 WL 1284735, at *8 (acknowledging that "courts in Michigan and elsewhere are consistent in holding that a surgical procedure generally does not qualify as an alternative design for purposes of a design defect claim"). Thus, the Court grants Defendants' Motion on this limited point in that to the extent Dr. Garely seeks to opine on evidence of alternative surgical procedures, the Court precludes his testimony.

As to Dr. Garely's opinions on the claimed alternative meshes, Defendants first argue that Dr. Garely has no data to suggest that polyvinylidene ("PVDF" or "Pronova")[6] would have been a better choice for Plaintiff as it is only a theoretical product for which no studies have been conducted. (Defs.' Mot. to Limit Case-Specific Dr. Garely 17.) Additionally, Defendants argue that the non-armed mesh that Dr. Garely proposes the implanting physician should have used, Uphold, was not available at the time of Plaintiff's surgery in 2008 because it was not cleared by the FDA until 2011. (*Id.* at 18 (citation omitted).) Defendants seek to exclude this testimony as unreliable and potentially, irrelevant. (*Id.* at 17-18.)

The Court disagrees. The existence of a safer alternative design is relevant, but not dispositive, for a design defect claim under Tennessee law. *Brown*, 318 F. Supp. 2d at 599. The Court finds persuasive the analyses of the numerous other courts in this MDL that have found similar expert testimony concerning these safer alternatives to be reliable. *See, e.g., Godreau-Rivera v. Coloplast Corp.*, No. 19-1807, 2022 WL 1120371, at *7 (D. Del. Apr. 14, 2022) (finding that Dr. Garely's experience with mesh products and review of medical literature and other product materials provide adequate bases for his opinion on alternative designs); *Hosbrook v. Ethicon, Inc.*, No. 20-88, 2022 WL 136740, at *4-5 (S.D. Ohio Jan. 12, 2022) (rejecting Ethicon's attempts to preclude testimony about PVDF as a safer alternative); *Sexton v. Ethicon, Inc.*, No. 20-282, 2021 WL 4138399, at *6 (E.D. Ky. 2021) (rejecting the argument that FDA approval is needed for a product to be a feasible, safer alternative); *Bell v. Ethicon Inc.*, 2021 WL 1111071, at *7 (S.D. Tex. 2021) (explaining that the fact that PVDF was not cleared by the

[6] Pronova, sometimes used interchangeably with PVDF (the underlying materials in Pronova), is a suture "indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures." (*See* https://www.jnjmedtech.com/en-US/product/pronova-poly-hexafluoropropylene-vdf-suture; Dr. Garely 4/15/16 Dep. Tr. 206:13-17, ECF No. 61-3 (further explaining the material).)

FDA does not render the testimony unreliable nor bear on whether PVDF mesh is a safer alternative to other mesh products); *Bellew v. Ethicon, Inc.*, No. 2:13-22473, 2014 WL 12685965, at *6 (S.D. W. Va. Nov. 20, 2014) (allowing testimony regarding PVDF as alternative polymer). To be sure, the Court is aware that many courts have also come out the other way. *See, e.g., Roeder v. Am. Med. Sys., Inc.*, No. 20-1051, 2021 WL 4819443, at *4 n.2; *8-9 (D. Kan. Oct. 15, 2021) (excluding opinions regarding PVDF given that it has not been approved for use in the United States); *see also Shostrom v. Ethicon, Inc.*, No. 20-1933, 2022 WL 900157, at *6 (D. Colo. Mar. 28, 2022) (excluding Dr. Garely's opinions regarding PVDF/Pronova as safer alternatives to the Prolift because the product was not available at the time of plaintiff's surgery).

More importantly, the Court recently rejected a similar argument that an alternative material identified by the plaintiff's expert was not "available" because the FDA had never "approved" a device using this material for treatment of stress urinary incontinence. *Dandy*, 2022 WL 1284735, at *12. As the Hon. Freda L. Wolfson, C.U.S.D.J., persuasively reasoned, "interpreting availability to require an FDA-approved product that implements the proposed alternative design would enable companies to avert liability by merely refraining from seeking FDA approval for designs they know to be safer, which would subvert the purpose underlying design defect law." (*Id.*) The Court recognizes Defendants' other concerns with the lack of citations offered by Dr. Garely, but Defendants are free to cross-examine Dr. Garely about these issues at trial. Ultimately, the Court finds unavailing Defendants' arguments on the exclusion of alternative meshes as potential alternatives and denies Defendants' Motion on this point.

Defendants finally take issue with Dr. Garely's acknowledgement that all surgeries come with concomitant medical risks, which they assert renders his opinions on alternatives unreliable. (Defs.' Mot. to Limit Case-Specific Dr. Garely 19.) But Defendants' "contention that injuries might still occur using an alternative procedure or product does not warrant the exclusion of . . .

[Dr.] Garely's opinions." *Godreau-Rivera*, 2022 WL 1120371, at *7. It is well accepted that any medical intervention brings risk. Challenges to the scientific rigor of Dr. Garely's opinions again go to the weight the factfinder may choose to give these opinions, not their admissibility. (*See id.*) The Court thus rejects Defendants' Motion on this point.

2. The General Causation Opinions and Testimony of Dr. Garely

Defendants next move to limit numerous general causation opinions and testimony of Dr. Garely. (*See* Defs.' Mot. to Limit Causation Dr. Garely 1, ECF No. 61-6.) The Court addresses each opinion and the grounds for its exclusion in turn.

a. Opinions on state of mind or mere historical commentary

Defendants first object that Dr. Garely speculatively claims to have knowledge of what risk information supposedly was available to Defendants and whether Ethicon acted reasonably in its warnings conduct. (*Id.* at 2.) In particular, Defendants take issue with several opinions that they allege are based on mere speculation, the testimony of others, and historical commentary. (*Id.*) As one example, Dr. Garely states: "In [the Prolift Instructions for Use] as well as its training and marketing materials, Ethicon made misleading representations to physicians that were contrary to its own internal documents which showed information known to or, at a minimum, available to Ethicon." (Dr. Garely MDL Expert Rep. 22, ECF No. 61-2.) In general, Dr. Garely seeks to opine on the inadequacies of the Patient Information Brochure for the Prolift kits as well as the adequacy of Ethicon's warnings to doctors. (*Id.* at 23-28.) Defendants further contend that nothing in Dr. Garely's training and experience as a pelvic surgeon enables him to testify about Defendants' state of mind. (Defs.' Mot. to Limit Causation Dr. Garely 3.) For example, Dr. Garely comments on Ethicon's process of withdrawing the Prolift kits from the market. (Dr. Garely MDL Expert Rep. 6-7.) In addition, Dr. Garely opines on the concerns raised by other physicians regarding the safety

profile of Prolift, as demonstrated by Ethicon's corporate documents and the shortcomings of several of Ethicon's clinical trials and lab studies. (*Id.* at 8-9, 13.)

Plaintiffs respond that Dr. Garely's testimony is admissible because Dr. Garely has not proffered any opinions that amount to legal conclusions or that refer to Defendants' state of mind, but rather, he simply references evidence, including corporate documents, to support his opinions on key issues. (Pls.' Opp'n to Mot. to Limit Causation Dr. Garely 8-9, ECF No. 70.)

The Court agrees with Defendants as to Dr. Garely's testimony concerning Ethicon's state of mind. "Experts may not provide testimony concerning the state of mind or culpability of [d]efendants." *Grande Village LLC v. CIBC Inc.*, No. 1:14-3495, 2018 WL 3085207, at *3 (D.N.J. June 22, 2018) (internal quotation omitted) (quoting *Krys v. Aaron*, 112 F. Supp. 3d 181, 203 (D.N.J. 2015)). In this litigation and others, district courts have routinely precluded experts from offering similar testimony. *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582209, at *5 (S.D. W. Va. Sept. 1, 2016) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.") (internal quotation omitted) (quoting *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004); *In Lewis v. Ethicon*, No. 12-4301, 2014 WL 186872, at *15 (S.D. W. Va. Jan 15, 2014) (finding that "expert opinions on Ethicon's knowledge or state of mind are not helpful to the jury" and that although plaintiffs' urogynecology expert was "qualified as a physician," he is not qualified to opine on Ethicon's state of mind or knowledge). The Court, accordingly, grants Defendants' Motion in that it excludes Dr. Garely's testimony as it relates to Defendants' alleged knowledge and state of mind (i.e., whether Ethicon was "misleading" and what Ethicon knew at the time it was developing its warnings and labeling).

Similarly, the Court agrees with Defendants that to the extent Dr. Garely's opinions simply rehash internal corporate documents, those opinions are not properly the subject of expert

testimony because they are lay matters. (*See* Dr. Garely MDL Expert Rep. 8-12.) "An expert may testify to a review of internal documents for the purpose of explaining the basis for his or her admissible opinions . . . [b]ut simply parroting [d]efendant's corporate documents or offering a narrative account of events from them will not be helpful to the jury." *Arevalo*, 2020 WL 3958505, at *21; *Highland Cap. Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 468-69 (S.D.N.Y. 2005) (excluding expert opinion that "rehash[ed] otherwise admissible evidence" that the jury was capable of understanding). Such testimony is properly presented through fact witnesses and documentary evidence. Accordingly, Dr. Garely may not merely parrot corporate documents but may, of course, rely on Defendants' documents to support otherwise admissible expert testimony. *See Arevalo*, 2020 WL 3958505, at *21 (finding that testifying expert may "explain[] technical terminology, draw[] inferences that would not be apparent to the lay person, and explain[] the basis of admissible opinions through commentary on documents and exhibits").

b. Opinions on product warnings

Defendants next seek to exclude Dr. Garely's opinions regarding the adequacy of product warnings. (Defs.' Mot. to Limit Causation Dr. Garely 7.) Defendants first contend that despite Dr. Garely's lack of familiarity with labeling regulations or verifiable expertise preparing product warnings, Dr. Garely offers numerous opinions regarding the alleged inadequacy of the Prolift Instructions for Use ("IFU"). (*Id.*) As examples, Defendants cite several of Dr. Garely's statements regarding the Prolift IFU, including: "In making an informed decision of whether or not to use a medical implant, the physician must be warned not only of the potential adverse events that may be associated with the product, but also of the frequency, severity, duration and potential permanence of adverse events." (Defs.' Mot. to Limit Causation Dr. Garely 8 (quoting Dr. Garely MDL Expert Rep. 22).)

Plaintiffs respond that Dr. Garely is qualified to testify about the adequacy of the Prolift warnings and instructions given not only his expertise in female pelvic health and reconstructive surgery generally and the use of mesh in female pelvic surgery specifically, but also, due to Dr. Garely's review of numerous IFUs for a variety of products, including Prolift. (Pls.' Opp'n to Mot. to Limit Causation Dr. Garely 11 (citing Dr. Garely MDL Expert Rep. 6, 21, 28).)

The Court agrees, in part, with Defendants. It is clear to the Court that Dr. Garely is not qualified as a general expert in product warnings and IFUs: he has never written IFUs, is "not familiar with what a [device] label would be," has limited experience reviewing regulatory guidance or regulations on the requirement of device labeling, has never reviewed FDA regulations pertaining to labeling and what needs to go into product IFUs, and does not know whether Ethicon had a particular labeling standard operating procedure. (Dr. Garely 4/15/16 Dep. Tr. 36:22-37:4, 38:23-41:19.) The Court finds Dr. Garely qualified, however, to testify on what risks he believes are associated with Prolift and whether they appeared on the product warnings.[7] The Court thus grants Defendants' Motion on this point in part. In sum, while Dr. Garely is qualified to testify about the risks associated with Prolift and whether those risks were adequately expressed in the device's IFUs, as well as the information typically included in IFUs and how physicians use that information, he shall not testify generally as to whether certain information should be included in

[7] As one court noted in addressing this same issue, "Dr. Garely is not an expert in the development of warning labels . . . the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582214, at *3. Or as a different court concluded, "Dr. Garely [was] qualified to testify about the risks associated with the [pelvic mesh] device and whether those risks were adequately expressed in the device's IFU, how physicians use IFUs, and the type of information typically included in IFUs . . . ." *Arevalo*, 2020 WL 3958505, at *5; *accord Godreau-Rivera*, 2022 WL 1120371, at *8 (D. Del. Apr. 14, 2022) ("Dr. Garely will be permitted to offer opinions as to whether [d]efendant's IFU provided adequate information about the risks associated with mesh implants, but he may not offer opinions as to what [d]efendant was, for example, 'obligated' to include in its IFUs.").

an IFU (including whether product warnings need to include the frequency, severity, and duration of adverse events).[8]

Similarly, Defendants contend that some of Dr. Garely's opinions lack citations and are thus, unreliable. (Defs.' Mot. to Limit Causation Dr. Garely 15.) As noted above, the Court rejects the argument that a lack of citations renders a statement per se unreliable given the expert's other methodological sources, including but not limited to the expert's own clinical experience.[9]

c. Opinions on FDA regulatory process and requirements

Next, Defendants seek to exclude Dr. Garely's opinions related to Ethicon's failure to comply with FDA regulatory processes and requirements on the basis that Dr. Garely is unqualified to do so. (Defs.' Mot. to Limit Causation Dr. Garely 18.) But the parties appear to agree that any opinions on FDA regulatory matters are inadmissible. (*See* Defs.' Reply Br. 7, ECF No. 80 ("First, it appears that Plaintiffs agree that any opinions on FDA regulatory matters are inadmissible.").) Because there is no dispute between the parties to resolve at this time, the Court denies as moot Defendants' motion to exclude testimony as to FDA regulatory opinions.

d. Opinions on the degradation of mesh

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[8] Defendants additionally contend that Dr. Garely has not set forth reliable bases for his opinions regarding the complications and risks about which Defendants should have warned. (Defs.' Mot. to Limit Causation Dr. Garely 14.) Defendants' objections here boil down to disagreement with the veracity of Dr. Garely's statements regarding Defendants' dissemination of certain information and warnings, and Dr. Garely's overall assessment of internal corporate documents. As to these allegations about falsities, the Court finds that "[a] disagreement of this sort is better sorted out through cross-examination." *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582214, at *3.

[9] Defendants' disagreement with the first statement of Dr. Garely's that Defendants identify in this section—regarding the pain associated with POP repair procedures versus mesh—appears to only be with Dr. Garely's conclusion stemming from his review of Defendants' internal documents. At this juncture, the Court lacks sufficient knowledge on where exactly Dr. Garely derives both this conclusion and his conclusion regarding the difficulty of removing Prolift mesh in its entirety. (*See* Defs.' Mot. to Limit Causation Dr. Garely 15 (internal citations omitted).) Thus, the Court reserves on ruling as to admissibility as to these opinions until trial.

Defendants contend that the Court should preclude Dr. Garely from rendering any opinion related to the alleged degradation of mesh because no reliable, objective evidence exists that Plaintiff's mesh degraded, so any expert opinion on degradation is irrelevant and should be excluded. (Defs.' Mot. to Limit Causation Dr. Garely 19-20.) Because Plaintiffs agree that Dr. Garely will not offer any opinions on mesh degradation, this portion of Defendants' Motion is denied as moot. (Pls.' Opp'n to Mot. to Limit Causation Dr. Garely 22-23 ("Defendants' motion on this issue is moot because Dr. Garely will not offer any opinions about mesh degradation.").)

e. Opinions on biomaterials or medical device design

Defendants next contend that Dr. Garely is not qualified to render opinions on biomaterials, polypropylene degradation, entrapment of tiny nerves in mesh pores, chronic foreign body reaction, adequate pore size, adequate weight of polypropylene, and biocompatibility of polypropylene. (Defs.' Mot. to Limit Causation Dr. Garely 21.) Dr. Garely admits that he is not a biomaterials engineer, a polymer scientist or pathologist, and he has never microscopically examined or performed testing on the mesh in Prolift. (Dr. Garely 4/15/16 Dep. Tr. 36:5-12; 86:2-87:3.) Defendants further contend that Dr. Garely has no particular medical device design expertise that would qualify him to opine that Prolift is defectively designed. (Defs.' Mot. to Limit Causation Dr. Garely 23 (internal quotations omitted).) Additionally, Defendants contend that Dr. Garely "employs an unreliable methodology by basing his materials opinions nearly entirely on his personal experience with only 10-20 mesh explants and his review of internal company documentation." (*Id.* at 24.)

The Court disagrees. Dr. Garely, a medical professor and surgeon, is qualified to testify on these issues. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582215, at *3 (rejecting similar arguments involving a challenge to Dr. Garely's opinion); *Godreau-Rivera*, 2022 WL 1120371, at *7 (rejecting mesh manufacturer defendant's motion seeking to exclude Dr.

Garely's design defect opinions, concluding that Dr. Garely's "experience in pelvic floor surgery and his familiarity with the complications caused by mesh products render[ed] him qualified to provide opinions on the design of mesh products," and further holding that "Dr. Garely's opinions [were] well-grounded in both his clinical experience in treating mesh complications. . . and in his review of [d]efendant's internal documents on mesh products"); *Swintelski v. Am. Med. Sys., Inc.*, No. 20-60410, 2021 WL 4527451, at *7 (S.D. Fla. Aug. 6, 2021) ("The Court agrees with [p]laintiff that Dr. Garely is qualified to render an expert opinion on whether the raw material polypropylene degrades or contracts within the human body. . . . Moreover, at least one court has allowed Dr. Garely to testify on the degradation and shrinkage of a related pelvic mesh device. . . . and [d]efendant has not identified a single case excluding Dr. Garely's proffered testimony on this issue."); *see also Jensen v. Am. Med. Sys., Inc.*, 2021 WL 6139631, at *6 (E.D. Wash. 2021) (plaintiff's pelvic surgeon expert qualified to opine on design defect issues in pelvic mesh case based on his "extensive experience with gynecological surgery, including at least 100 mesh explant procedures").) Based on Dr. Garely's extensive clinical and professional experience, the Court denies Defendants' Motion on this point.

f. Opinions on alleged safer alternative designs

Finally, as with Defendants' motion to limit testimony on alleged safer alternative designs as applied to Plaintiff, Defendants now seek to exclude Dr. Garely's general opinions on alleged safer alternative designs as unreliable and irrelevant. (Defs.' Mot. to Limit Causation Dr. Garely 25.) Dr. Garely contends that the following are "safer feasible designs": the use of native tissue repairs, or non-surgical POP treatment like Kegel exercises and pessaries, as well as alternatives to the design of the Prolift kits, such as: "the elimination of the mesh arms; elimination of the armed, blind trocar implantation design;" and the possible use of alternative materials, such as biologic materials or PVDF/Pronova. (Dr. Garely MDL Expert Rep. 29.) Defendants argue that

the alternatives are unreliable in that Dr. Garely cites no testing, data, or literature to support his opinions and that the opinions are irrelevant as to whether the Prolift was unreasonably dangerous. (Defs.' Mot. to Limit Causation Dr. Garely 26-27.)

The Court found above that Dr. Garely may not testify on alternative surgical procedures but may testify as to alternative meshes and products, including PVDF/Pronova. The Court adds that native tissue repairs and "biologics," including abdominal sacrocolpopexy, are not manufactured products/alternative designs, especially given their potential to confuse the jury, and thus, grants Defendants' Motion as to these points, precluding Dr. Garely from testifying about these treatments. *See, e.g.*, *Davis v. Johnson & Johnson*, No. 2:20-2635, 2022 WL 2116236, at *2 (D. Kan. June 9, 2022) (excluding Dr. Garely's sacrocolpopexy alternative design opinion because it is an alternative procedure and excluding expert's opinion on natural tissue as a procedure); *Burton v. Ethicon Inc.*, 2021 WL 1725514, at *2 (E.D. Ky. 2021) (finding that "abdominal sacrocolpopexy with mesh or biologic products" and fascia [POP] repair with "Biologics" are "not alternative designs for Prolift [but instead] entirely different procedures").

As for Dr. Garely's opinions on the elimination of the mesh arms and the elimination of the armed, blind trocar implantation design, the Court is unclear whether Dr. Garely believes these to be a safer alternative when implanted transvaginally (i.e. how Prolift is used) or as part of an abdominal sacrocolpopexy, which the Court has found to be an alternative surgical procedure. *See Burton*, 2021 WL 1725514, at *2. Plaintiffs seem to suggest that Dr. Garely is advocating a non-armed mesh implanted "using the sacrocolpopexy procedure." (Pls.' Opp'n to Mot. to Exclude Causation Dr. Garely 37; *see also* Dr. Garely 4/15/16 Dep. Tr. 73:17-74:1 (Dr. Garely testifying that he doesn't believe that mesh should be implanted vaginally to treat prolapse regardless of use of mesh arms, trocars, or pore size).) "To the extent that is the case, that would again be an alternative procedure that is not relevant to [p]laintiff's design-defect claim." *Davis*,

2022 WL 2116236, at *2 (discussing testimony regarding the elimination of the mesh arms and the armed, blind trocar implantation design).[10] Accordingly, Defendants' motion to exclude Dr. Garely's alternative design opinions on these points is granted.

Similarly, the Court grants the portion of Defendants' motion related to Kegel exercises and pessaries, which the Court finds are irrelevant to purported defects in Prolift. *See Shostrom*, 2022 WL 900157, at *5 (excluding as irrelevant Dr. Garely's opinions regarding Kegel exercises and the use of a pessary).

3. The Opinions and Testimony of Dr. Klosterhalfen

Finally, Defendants move to limit the testimony of Dr. Klosterhalfen on several grounds. (*See generally* Defs.' Mot. to Limit Dr. Klosterhalfen, ECF No. 62-8.) They concede, however, that they do not challenge Dr. Klosterhalfen's qualifications as a pathologist. (*Id.* at 1.)

a. Opinions on degradation and particle loss

Defendants first contend that Dr. Klosterhalfen's opinions on degradation and particle loss should be excluded as unreliable. (*Id.* at 5.) Dr. Klosterhalfen states that polypropylene "degrades *in vivo* over time" and that this degradation increases the inflammatory reaction following implementation of the device, resulting in "scarification, contraction of tissues, and pain." (Dr. Klosterhalfen Expert Rep. 29, 34, ECF No. 62-2.) Dr. Klosterhalfen bases his opinions on his general knowledge as a pathologist, including his personal experience examining tissue samples and review of several medical studies. (Dr. Klosterhalfen 11/10/13 Dep. Tr. 444:13-445:18, ECF No. 62-3.) But Defendants highlight that Dr. Klosterhalfen fails to identify the relevant studies underlying his opinion. (Defs.' Mot. to Limit Dr. Klosterhalfen 6.)

[10] To the extent either party asserts that the Court misinterprets Dr. Garely's opinions here, the parties may revisit this issue at trial.

The Court disagrees with Defendants' contention. Dr. Klosterhalfen is a pathologist who has studied the body's responses to implanted devices and how the devices influence biocompatibility. (Dr. Klosterhalfen Expert Rep. 2.) He also served as a consultant to Ethicon beginning in the mid-1990s and is "a key opinion leader in the field of surgical pathology and the biological response to implantable surgical mesh materials." (*Id.*; *see generally* Dr. Klosterhalfen CV, ECF No. 71-2.) Dr. Klosterhalfen explains in detail the bases for his opinion on degradation and its effects, including his review of several published studies on this subject and his own involvement in projects studying the inflammatory effects of polymeric particle debris on macrophages; he also discusses how he has "personally performed scanning electron microscopy of vaginal mesh explants and hernia mesh explants and made the same findings." (Dr. Klosterhalfen Expert Rep. 29-30.) And he discusses his own review of Ethicon's studies performed in the 1980s and 1900s in which Ethicon found evidence of degradation. (*Id.* at 30-31.) Dr. Klosterhalfen's extensive clinical experiences and review of the literature and Ethicon's own studies are sufficient bases for Dr. Klosterhalfen's opinions. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 622 (S.D. W.Va. 2013), *on reconsideration in part* (June 14, 2013) (holding upon motion for reconsideration that Dr. Klosterhalfen relied on sufficient and reliable bases for his opinions that degradation occurs in polypropylene and the general effects of polypropylene degradation and could testify about these topics generally); *cf. In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2014 WL 186872, at *10 (S.D. W. Va. Jan. 15, 2014) (reserving ruling for trial on Dr. Klosterhalfen's opinions on degradation where his expert report failed to cite to specific studies on this topic).

Defendants also contend that his opinions are irrelevant because "he does not specifically indicate in his report that [Plaintiff]'s mesh degraded or lost particles." (Defs.' Reply Br. 3, ECF No. 82.) But "Ethicon chose not to depose Dr. Klosterhalfen in this case," and such deposition

testimony may have elucidated further his opinions on Plaintiff's condition. (Pls.' Opp'n to Mot. to Limit Dr. Klosterhalfen 19, ECF No. 71.) In any event, Dr. Klosterhalfen, who opines on the chronic inflammatory response as it relates to the degradation of mesh and reviewed Plaintiff's pathology, does conclude that "it is my opinion to a reasonable degree of medical and scientific certainty that she suffered from a chronic inflammatory response as a result of having had the Prolift Total implanted in her." (Dr. Klosterhalfen Expert Rep. 6-7.) Thus, the Court does not find Defendants' argument persuasive. The Court, accordingly, denies Defendants' Motion on this point.

b. Opinions on effective porosity

Defendants next contend that Dr. Klosterhalfen's opinions on effective porosity should be excluded as unreliable and irrelevant. (Defs.' Mot. to Limit Dr. Klosterhalfen 7.) Dr. Klosterhalfen previously testified that mesh, when put under stress, decreases the pore size, and to have "effective pore[s] after implantation," meaning after the mesh has been "integrated into the body, and under mechanical load, the mesh still has to have mesh or pore sizes or open pores with [one] millimeter." (Dr. Klosterhalfen 2/2/14 Dep. Tr. 46:7-25, 47:11-25, ECF No. 62-4.) He further opined that to ensure mesh maintains an "effective porosity" of at least one millimeter, pristine mesh—or mesh that has not yet been implanted in the human body—must have pores that are three millimeters or larger. (*See id.* at 46:15-22.) Dr. Klosterhalfen concludes that the Prolift device mesh has too small of pores, leading to complications. (Dr. Klosterhalfen Expert Rep. 17.)

Defendants contend that his opinions on effective porosity are unreliable because they have not been validated; Dr. Klosterhalfen himself has admitted that there are no "clinical studies" on the topic and has previously written an article defining a 1.6-millimeter pore as large, rather than minimal. (Defs.' Mot. to Limit Dr. Klosterhalfen 8-9 (citations omitted).) Defendants contend, moreover, that the effective porosity concept is irrelevant to the case because Dr. Klosterhalfen

"cannot say that the effective porosity testing replicates the type of forces that were applied to [Plaintiff]'s mesh." (Defs.' Mot. to Limit Dr. Klosterhalfen 10-11.)

The Court disagrees and finds Dr. Klosterhalfen's opinions both relevant and reliable. As for reliability, his expert report contains an extensive explanation of his opinions, citing to numerous peer-reviewed, published opinions and detailing his and his colleagues' extensive study and own published work on these topics. (Dr. Klosterhalfen Expert Rep. 12-20.) He also explains that his "findings are consistent with [his] own study of the pathology of thousands of mesh explants with varying pore sizes, including the pathology [he has] reviewed specific to the cases in this litigation." (*Id.* at 13.) And as noted above, Defendants do not contest Dr. Klosterhalfen's qualifications as a pathologist. Again, a witness may be qualified as an expert by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. For the above reasons, the Court thus finds Dr. Klosterhalfen has sufficient, reliable bases for his opinions. *See also In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 619-20 (rejecting *Daubert* motion to exclude Dr. Klosterhalfen's testimony on pore size).

As for relevancy, Dr. Klosterhalfen's opinions related to pore size are properly applied to the facts of this case. The Court remains unconvinced by Defendants' attempts to argue that Dr. Klosterhalfen's opinions from years ago in another case demonstrate why he should not be allowed to testify in this matter. Again, Dr. Klosterhalfen has explained how he reviewed Plaintiff's pathology in coming to his conclusion that the Prolift's pore size design has contributed to Plaintiff's clinical complications. (Dr. Klosterhalfen Expert Rep. 6-7.) That is all that is required. The Court thus denies Defendants' Motion on this point.

c. Opinions on Ethicon's state of mind

Defendants next contend that Dr. Klosterhalfen's opinions about risk information that was supposedly available to Ethicon, and as to various design characteristics, issues, and outcomes that

he claims Ethicon "recognized," are improper opinions about Ethicon's state of mind. (Defs.' Mot. to Limit Dr. Klosterhalfen 11.) But Defendants fail to identify any specific opinions of Dr. Klosterhalfen that they wish to exclude. (*See generally id.*) In any event, Plaintiffs state that "Dr. Klosterhalfen will not testify regarding 'Ethicon's state of mind,'" so the Court denies as moot Defendants' Motion on this point. (Pls.' Opp'n to Mot. to Limit Dr. Klosterhalfen 23.)

d. Opinions on alternative designs

Next up, Defendants seek to exclude Dr. Klosterhalfen's opinions that an alternative mesh design using PVDF/Pronova would be safer for use in prolapse repair. (Defs.' Mot. to Limit Dr. Klosterhalfen 14 (citing Dr. Klosterhalfen Expert Rep. at 40-44).) Defendants' arguments on this testimony simply rehash their arguments above in seeking to exclude similar testimony on alternative designs from Dr. Garely. Defendants do not challenge Dr. Klosterhalfen's qualifications to offer this testimony—rather, they again challenge his opinions on PVDF/Pronova as unreliable and unhelpful. (*See* Defs.' Mot. to Limit Dr. Klosterhalfen 15.) The Court thus hereby incorporates by reference its discussion above. In addition, the Court finds sufficient Dr. Klosterhalfen's methodology in coming to his conclusion. He discusses and explains the availability and safety advantages of PVDF to polypropylene in his Expert Report, including his own peer-reviewed, published articles, his own research, and Ethicon's own studies, in some of which Dr. Klosterhalfen participated. (Dr. Klosterhalfen Expert Rep. 40-44.) The Court, accordingly, denies Defendants' Motion on this point.

e. Opinions on personal data pools

Defendants seek to preclude Dr. Klosterhalfen from offering any testimony reliant on his personal data pools on the bases that: (1) he has previously refused to disclose the underlying database; (2) his testimony is irrelevant and unduly prejudicial; and (3) his database is unreliable. (*See* Defs.' Mot. to Limit Dr. Klosterhalfen 16-20.) In forming his opinions, Dr. Klosterhalfen

relies on a database he has developed from his own personal collection of explanted devices and tissue samples, including 6,000 hernia mesh explants and 1,500 vaginal mesh explants. (Dr. Klosterhalfen Expert Rep. 4.) As one example, Dr. Klosterhalfen opines that the contraction of tissues, shrinkage, and other issues he has observed in polypropylene mesh "are consistent with those [he has] seen in [his] data pool of vaginal mesh explants." (Dr. Klosterhalfen Expert Rep. 10.)

To start, the Court disagrees that Dr. Klosterhalfen's previous refusal to disclose his underlying database warrants exclusion of his current testimony. Defendants' only evidence on his refusal comes from Dr. Klosterhalfen's deposition testimony in 2013, in which he declined to produce his personal explant database, but since then, Dr. Klosterhalfen has provided additional testimony further explaining the methodology behind his database. (Pls.' Opp'n to Mot. to Limit Dr. Klosterhalfen 38.) And in this case, Plaintiffs contend, with no rebuttal from Defendants, that Dr. Klosterhalfen produced data compilations from both his hernia mesh data pool and his pelvic mesh data pool. (*Id.* (citing Dr. Klosterhalfen Expert Rep. 4-5); *see also* Ex. 6, ECF No. 71-7; Ex. 7, ECF No. 71-8.) Thus, Defendants' argument on this point is unavailing.

Second, the Court disagrees that Dr. Klosterhalfen's testimony here is irrelevant and unduly prejudicial. Dr. Klosterhalfen began to work on his pelvic mesh data pool in 2004, during which time he served as a consultant for Defendants, as part of his independent research on surgical mesh. (Dr. Klosterhalfen Expert Rep. 3-4.) Defendants claim that "[of] the approximately 1,500 tissue samples from vaginal repairs in [Dr.] Klosterhalfen's data pool, it is entirely unclear which or how many of those samples relate directly to the Prolift Total device or the specific polypropylene mesh utilized in this device," and that his testimony on this point is therefore, irrelevant. (*See* Defs.' Mot. to Limit Dr. Klosterhalfen 17.) But his failure to directly rely on specific samples in relation to Prolift renders his opinions on the matter *less* prejudicial to Plaintiffs, and Defendants are free

to cross-examine Dr. Klosterhalfen about alleged flaws or weaknesses concerning the factual underpinnings for his opinions. *See Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab. Litig. v. Ethicon, Inc.*, No. 1:17-2782, 2020 WL 9887566, at *5 (N.D. Ga. Dec. 4, 2020) (permitting Dr. Klosterhalfen's testimony on data pools due, in part, to a lack of specific reliance on them in forming his opinions for the mesh at issue). Thus, Defendants' argument on this point is equally unavailing.

Third, and finally, the Court rejects Defendants' argument that Dr. Klosterhalfen's database is unreliable. For one, the findings from Dr. Klosterhalfen's "data pool" have been published in several peer-reviewed journal articles. (Pls.' Opp'n to Mot. to Limit Dr. Klosterhalfen 35 (citing several medical journals).) Other courts have also found his testimony on data pools sufficiently reliable to warrant inclusion. *See Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab. Litig.*, 2020 WL 9887566, at *5. And at the end of the day, Defendants' objections go to the weight of his testimony, rather than its admissibility. (*See id.*) The Court denies Defendants' Motion to exclude Dr. Klosterhalfen's opinions reliant on his personal data pools.

f. Specific causation opinions

Last, Defendants allege that Dr. Klosterhalfen is unqualified to offer specific causation opinions related to Plaintiff's claimed injuries. (*See* Defs.' Mot. to Limit Dr. Klosterhalfen 20.) Dr. Klosterhalfen concludes that "the lack of effective porosity, large surface area polypropylene design of Prolift Total and the arms inevitably implanted under tension are significant contributing causes for erosion, infection, chronic inflammation, contraction of tissues, pain, nerve damage, permanent and excessive scar tissue in [Plaintiff]." (Dr. Klosterhalfen Expert Rep. 34.) Defendants contend that Dr. Klosterhalfen's position as a surgical pathologist in Germany, rather than as a surgeon or clinician treating women with POP in the U.S., renders him unqualified to offer such testimony. (*See* Defs.' Mot. To Limit Dr. Klosterhalfen 22.) They also contend that Dr.

Klosterhalfen's failure to have performed a POP repair and publish on this issue, as well as other gaps in experience, render Dr. Klosterhalfen unqualified. (*Id.*)

The Court rejects this argument and finds Dr. Klosterhalfen qualified to offer specific causation opinions. The Court will not spill any more ink detailing Dr. Klosterhalfen's background, except to take note that others, including from Ethicon, have noted he is one of "the most renowned surgical pathologist[s] and mesh expert[s] in the world." (*See* Pls.' Opp'n to Mot. to Limit Dr. Klosterhalfen 3.) And in case it bears repeating, districts courts—including, now, this one—concluded time and time again that pathologists are qualified to opine on specific causation in pelvic mesh cases. *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 589 ("Dr. Klosterhalfen's very job as a pathologist qualifies him to opine on [medical causation]."); *Tyree*, 54 F. Supp. 3d at 531 ("[A]s I have explained previously, a pathologist's job is to determine medical causation.") Thus, the Court denies Defendants' Motion on this point.

IV. CONCLUSION

For the reasons stated above, the Court denies Plaintiffs' Motion with respect to Dr. Wagner; denies Plaintiffs' Motion with respect to Dr. Winfree; denies Plaintiffs' Motion with respect to Dr. Wright; grants-in-part and denies-in-part Defendants' Motion to Limit Case-Specific Opinions and Testimony of Dr. Garely; grants-in-part and denies-in-part Defendants' Motion to Limit General Causation Opinions and Testimony of Dr. Garely; and denies Defendants' Motion with respect to Dr. Klosterhalfen.

/s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE